February 2010

Alabama State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

10 Inverness Center, Suite 110 • Birmingham, AL 35242 • Tel: 205/981-2280
Fax: 205/981-2330

Fifty-Year 'Gold Year' Pharmacists

Name	Original Licensure
Ted Blair Ratcliff	1/1/1960
Derel Gray Till	3/23/1960
John Thomas Reading	4/19/1960
Joe Nix Quin	4/19/1960
Harriett Ann Ginn	4/19/1960
Carole F. Spremich	4/25/1960
John Richard Sawyer	5/16/1960
Martha Hinton Legg	5/16/1960
George Richard Bolling	6/2/1960
James Walter Gregg	6/14/1960
William Ralph McKinnon, Jr	6/14/1960
Eugene Allen Mattox	7/1/1960
Charles Thurman Solomon	7/1/1960
Carl Vernon Tanner, Jr	7/1/1960
Charles Wesley Turner	7/1/1960
James Moody Brock	7/1/1960
Edward Owen Duke	7/1/1960
Mary Maynard Morrow	7/26/1960
William Earl Knight, Jr	8/16/1960
Roy Alexander Barnett, Jr	9/15/1960
Thomas Alex McLeod	9/29/1960
William Earl Baird	9/29/1960
James H. Whatley	10/14/1960
William Howard Hudgens	10/14/1960
Ray Delano McDiarmid	10/14/1960
Jake Ronald Vaughn	10/17/1960
Roy Wise McClendon, Jr	10/18/1960
William Henry McLain, Jr	10/28/1960
James Edward Askew	11/7/1960
Daniel McFerrin	11/9/1960
James Lewis Smith	12/9/1960

The preceding individuals are being recognized for their distinction of having been licensed pharmacists in Alabama for 50 years. The Alabama State Board of Pharmacy gratefully acknowledges their years of contribution to the learned pharmacy profession.

Board Members/Drug Inspectors – 2010

Mike Mikell, President.....Millbrook
Dr Rob Nelson, Vice President ..... Tuscumbia
Donnie Calhoun, Treasurer.....Anniston
Kenny Sanders, Member .....Alabaster
Mark Conradi, Member .....Clanton
Herbert Bobo, Secretary .....Birmingham
Henry Burks, Jr, Chief Inspector..... Hoover
Eddie Braden, Inspector.....Birmingham
Scott Daniel, Inspector .....Prattville
Mark Delk, Inspector ..... Pelham
George Grubbs, Inspector..... Springville
Richard Lambruschi, Inspector .....Harvest
Glenn Wells, Inspector ..... Trussville

USP Chapter 797 Pharmaceutical Compounding – Sterile Products – Question & Answer

1. **Question:** Is it a requirement that Alabama pharmacies preparing compounded sterile products (CSPs) follow United States Pharmacopeia (USP) Chapter 797 guidelines?

   Answer: Yes. The Board compliance date is December 31, 2010.

2. **Question:** Can a pharmacy prepare "anticipated need" CSPs under the immediate-use provision of USP Chapter 797 and claim exemption from "Low-Risk Level CSPs" guidelines?

   Answer: The following information is taken from United States Pharmacopeia Chapter 797, "Pharmaceutical Compounding – Sterile Preparations" in the section on "Immediate-Use CSPs":

   "The immediate-use provision in intended only for those situations where there is a need for emergency or immediate patient administration of a CSP. Such situations may include cardiopulmonary resuscitation, emergency room treatment, preparation of diagnostic agents, or critical therapy where the preparation of the CSP under

Continued on page 4

FDA and ISMP Warn of Potential Medication Errors for Dosing and Emergency Compounding of Tamiflu

Food and Drug Administration (FDA) issued a Public Health Alert regarding potential dosing errors with Tamiflu® (oseltamivir) for oral suspension. While United States prescriptions for liquid medicines are generally written in milliliters or teaspoons, Tamiflu is dosed in milligrams and packaged with a dispenser marked in milligram dosages. Errors where dosing instructions for the patient do not match the dosing dispenser have been reported to FDA. FDA advises that providers should write doses in milligrams if the dosing dispenser with the drug is in milligrams. Pharmacists should ensure that prescription instructions and the dosing device use the same unit of measure. More information can be accessed at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm183714.htm.*

The Institute for Safe Medication Practices (ISMP) issued an alert to all health care professionals regarding a risk of dosing errors related to the concentration of pharmacy-compounded Tamiflu (oseltamivir phosphate) oral suspension being dispensed due to shortages of the manufacturer's oral suspension. The base concentration for the commercially manufactured Tamiflu oral suspension is 12 mg/mL. The directions for emergency compounding of Tamiflu oral suspension from Tamiflu powder capsules result in a 15 mg/mL oseltamivir base concentration. Incidents have occurred resulting in too large of a dose being dispensed to children. ISMP advises that prescribers communicate suspension doses in milligrams rather than by volume, and that, if experiencing shortages of commercial Tamiflu oral suspension, pharmacists communicate with area medical practices regarding the dosage error risk. More information may be found at the ISMP Web site at *www.ismp.org/safetyalerts/20091015-Tamiflu.asp*.

FDA Authorization for Use of Outdated Tamiflu Products Remains in Effect until April 2010

On October 30, 2009, FDA issued an Emergency Use Authorization (EUA) allowing pharmacists to dispense certain lots of expired Tamiflu for oral suspension as part of the federal government's response to the 2009 H1N1 influenza public health emergency. The declaration of emergency justifying the EUA remains in effect until April 26, 2010, unless it is terminated earlier, or extended. The authorized lots of Tamiflu for oral suspension, which were tested through the federal government's Shelf-Life Extension Program, are part of the Strategic National Stockpile and are listed on the FDA Web site at *www.fda.gov/NewsEvents/PublicHealthFocus/ucm154962.htm*. Additional information for health care professionals and the EUA letter are also available on the FDA Web site.

HIPAA and Quality – The Seven-Year Itch

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. *ISMP is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also a FDA MedWatch partner. Call 1-800-FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at* www.ismp.org. *ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

On April 24, 2003, an article in the *Wall Street Journal* noted that many health care providers "are going overboard to avoid violations" of the Health Insurance Portability and Accountability Act (HIPAA) privacy rule, which took effect on April 14 of that year. In fact, initial concern was that the rule might actually slow the transfer of protected health information and place patients at risk for harm, certainly the opposite of HIPAA's intended goal.

One particularly troubling area of confusion is whether listing the drug's intended purpose on a prescription violates the privacy rule. Initially, numerous organizations reported that physicians were reluctant to include this crucial information on prescriptions. But according to the US Department of Health and Human Services (HHS), listing a medication's purpose or the patient's diagnosis on a prescription does not violate the privacy rule. Although a patient's diagnosis or purpose for using a medication would qualify as protected health information, communicating this information on a prescription does not require separate, special authorization because the information is used for the purposes of treating the patient. A violation would occur only if the prescription form was then used for a purpose not defined by the HIPAA privacy rule, such as copying it for a marketing company.

Concerns were also raised that listing a purpose on prescriptions did not meet qualifications of providing only the minimum amount of information necessary to treat the patient. However, the "minimum necessary" rule does not apply when protected health information is disclosed between providers treating the same patient. ISMP firmly believes that the drug's intended purpose should be part of the "minimum amount of information necessary" on a patient's prescription. Pharmacists should never be expected to dispense a medication without knowing its intended use, which is typically the case in many community pharmacies. Knowing the

medication's purpose helps pharmacists avoid confusion between products with look-alike names, as most products with similar names are used for different purposes. It also allows a double check to occur because the pharmacist is able to verify that the medication is being used appropriately for the patient's condition, and that it is dosed properly for its intended use.

The same arguments hold true for medication reconciliation. It is not a violation of the HIPAA privacy rules for community pharmacies to share patient information for the purposes of reconciling a patient's medication profile with hospitals because the minimum necessary rule does not apply when protected health information is disclosed between providers treating the same patient.

Seven years later, the best advice is still to use common sense when applying the HIPAA rules so that patient privacy and safety are not compromised.

USP Standards for Heparin Products May Require Dosage Adjustments

Heparin products using new standards began shipping on October 8, 2009, and may require that dosages are adjusted to achieve consistent potency, according to a FDA alert. New manufacturing controls issued by United States Pharmacopeia (USP) were adopted for heparin to guard against potential contamination. Included in the new controls were changes in the unit dose, making heparin about 10% less potent than the former unit used. More information can be found at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm184674.htm*.

FDA Issues Alert, Seeks Assistance in Tracking Stolen Tylenol Arthritis and Tylenol PM Caplets

FDA has issued an alert regarding stolen Tylenol® Arthritis and Tylenol® PM products. Pharmacists should be wary of the following Tylenol products:

- Tylenol Arthritis Pain Caplet 150 count bottles with the following identifying information: UPC number 30300450838155, code number 8381500, and lot number 09XMC112.
- Tylenol PM 2-caplet packets with the following identifying information: UPC number 30300450482304, code number 4823000, and lot number 09XMC110.

The theft took place at a cargo terminal at the Jacksonville Port Authority in Jacksonville, FL on September 25, 2009.

FDA seeks assistance in tracking this theft and is asking pharmaceutical drug distributors and pharmacies that may receive offers for the stolen drug products, or that may have been sold stolen product, to contact FDA's Office of Criminal Investigations (OCI) by phone at 800/551-3989 or on the OCI Web site at *www.fda.gov/ICECI/CriminalInvestigations/ucm123025.htm*. Pharmacists should verify pedigrees they receive with any wholesale drug purchases. News regarding the alert can be found at *www.fda.gov/ICECI/CriminalInvestigations/ucm186269.htm*.

FDA Warns Companies to Stop Marketing Unapproved Codeine Sulfate Tablets

On October 13, 2009, FDA warned four companies to stop marketing unapproved codeine sulfate tablets. The manufacturers and distributors that received warning letters are as follows:

- Lehigh Valley Technologies Inc in Allentown, PA
- Cerovene Inc in Valley Cottage, NY
- Dava International Inc in Fort Lee, NJ
- Glenmark Generics Inc USA in Mahwah, NJ

FDA regulations allow manufacturers 90 days to cease manufacturing of new product, and distributors 180 days to cease further shipment of existing products. Previously manufactured unapproved products may still be found on pharmacy shelves for a period of time. FDA advises that Roxane Laboratories markets FDA-approved codeine sulfate tablets and is able to meet the demand for the drug. For additional information about the warning letters, visit *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm186418.htm*.

2010 Survey of Pharmacy Law Now Available

Serving as a convenient reference source for individuals seeking an overview of the state laws and regulations that govern pharmacy practice, the updated 2010 *Survey of Pharmacy Law* is now available.

The *Survey*, produced as a CD, consists of four sections including a state-by-state overview of organizational law, licensing law, drug law, and census data. Newly added this year, a question in Section 17, "Wholesale Distributor Licensure Requirements," asks whether or not states license or register manufacturers separately from wholesalers.

Updates for the *Survey* were graciously provided by the state boards of pharmacy. In addition to the state boards of pharmacy's support, this year NABP requested data from numerous outside organizations for the *Survey's* prescribing authority and dispensing authority laws in Sections 24 and 25.

The *Survey* can be purchased for $195 by visiting the publications section of the NABP Web site at *www.nabp.net*, downloading the publications order form, and mailing it to NABP Headquarters with a check or money order made payable to NABP. Credit card payments are accepted by phone.

All final-year pharmacy students receive the *Survey* free of charge through the generous sponsorship of Purdue Pharma L.P.

For more information on the *Survey*, please contact customer service via phone at 847/391-4406 or via e-mail at custserv@nabp.net.

Continued from page 1

conditions described for 'Low-Risk Level CSP's' subjects the patient to additional risk due to delays in therapy. Immediate-use CSPs are not intended for storage for anticipated needs or batch compounding. Preparations that are medium-risk level and high-risk level CSPs shall not be prepared as immediate-use CSPs."

3. **Question:** Can ADVANTAGE® drug delivery or other similar systems requiring assembly according to the manufacturer's guidelines be utilized at the bedside and meet USP Chapter 797 guidelines?

   Answer: Yes. Sterile delivery systems engaged according to the manufacturer's guidelines with immediate administration meet USP Chapter 797 preparation guidelines.

Rule Change Effective January 13, 2010

680-X-2-.14 The Role of Technicians in Pharmacies in Alabama

(10) All pharmacy technicians shall register with the Alabama State Board of Pharmacy. This registration shall expire on December 31 of odd numbered years . . . In the event an application for renewal of a pharmacy technician's registration is not received by December 31 of any odd numbered year but is received at the Board office no later than January 31 of the following year, a non-disciplinary administrative penalty in the amount of $30.00 must be paid in order to renew. This penalty is in addition to any penalty referenced above.

680-X-2-.19 Parenteral Therapy

(2) Registration and Certification, Pharmacies: All pharmacies engaged in the compounding of parenterals shall be registered with the Alabama State Board of Pharmacy annually and receive a permit in accordance with Code of Alabama 1975, §34-23-30.

(3) Registration and Certification, Pharmacists: All pharmacists engaged in compounding and dispensing or Parenteral Solutions including cytoxic agents shall register annually with the Board of Pharmacy in accordance with the Code of Alabama 1975, §34-23-51, 34-23-52.

(a) It shall be the responsibility of the supervising pharmacist to verify the parenteral certification of pharmacists involved in the preparation of parenteral products.

Transcription Attentions/Error Alerts/Safety Tips

1. Computerized physician order entry (CPOE) enhances the legibility of physician penmanship but can lead to computerized prescribing issues.
   - ♦ Shortcut computer abbreviations should always be clarified.

   Example: X7D. Is it for 7 days or 7 doses? **Clarify.**
   Example: QID or Q1D. They look so similar when t yped. Four times a day or every one day? Was it a selection error? **Clarify.**
2. Verbal orders should be transcribed immediately to writing. Writing may be transcribed directly into the pharmacy computer.
   - ♦ Implement a verbal order **read back** process to allow for verification and **clarification** during transcription to paper or computer.
3. Controlled substances Schedules III through V prescriptions sent via electronic transmission (e-prescribing) are not valid according to Drug Enforcement Administration regulation. **Faxed hard copy** controlled substances Schedules III through V prescriptions with a written physician signature are valid.
4. Clarification of prescription validity is between the pharmacist and the prescriber.

Board Meeting Dates 2010

Board meetings are open and held at the Board office.

Day 1 – Administrative Hearings – 8 AM

Day 2 – Board Business/Interviews – 8 AM

January 5-6, 2010	July 27-28, 2010
February 23-24, 2010	August 24-25, 2010
March 23-24, 2010	September 21-22, 2010
April 20-21, 2010	October 12-13, 2010
May 18-19, 2010*	November 16-17, 2010
June 22-23, 2010	December 14-15, 2010

* May 18-19, 2010, Day 1 and Day 2 activities in reverse

21 CRF §1306.23 Partial Filling of Prescriptions

The partial filling of a prescription for a controlled substance listed in Schedule III, IV, or V is permissible, provided that:

(a) Each partial filling is recorded in the same manner as a refilling,

(b) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed, and

(c) No dispensing occurs after 6 months after the date on which the prescription was issued.

The *Alabama State Board of Pharmacy News* is published by the Alabama State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

Joyce C. Altsman, RPh - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Larissa Doucette - Communications Manager

National Association of Boards of Pharmacy Foundation, Inc
1600 Feehanville Drive
Mount Prospect, Illinois 60056

ALABAMA STATE BOARD OF PHARMACY

Presorted Standard
U.S. Postage
PAID
Chicago, Illinois
Permit No. 5744